Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/501,698	**Applicant(s)** UEDA ET AL.	
	Examiner SATYENDRA K. SINGH	**Art Unit** 1657	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112-second rejection of record.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *29,31,33,34,36,39-41,46,49,51,61,64,66,67 and 69-78*.
   Claim(s) withdrawn from consideration: *1,2,4,8,12,13,15,17,20 and 28*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 9/10/09 considered.
13. ☐ Other: _____.

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657

Continuation of 11. does NOT place the application in condition for allowance because: In the interest of compact prosecution, current amendments to claims and 132 declaration presented by applicants have been entered. Applicant's current amendments to the claim 29 overcome the 112-second rejection of record. However, instant claim 29 as amended raises new issues under 112-second, such as improper Markush group in said claim 29, and issues of antecedent basis for the term "the fat and oil component" in claims 33 and 61, for example. In addition, the recitation of claim 29 as currently presented requires "reduced coenzyme Q10, a polyglycerol fatty acid ester, and a fat component, an oil component and/or a polyol", which is confusing as to what exactly is encompassed in the claimed composition, and needs further amendment for clarifying the same.

Applicants arguments regarding the obviousness rejection of record (see remarks, pages 9-11 and 132 declaration filed on 10/29/09 by Takahiro Ueda) have been fully considered, however they are not found to be persuasive for the following reasons of record:
Applicant's remarks on page 9, last paragraph regarding the beneficial results of incorporation of "polyglycerol fatty acid ester" that enhances "absorbability of reduced coenzyme Q10 in the living body without inhibiting the reduced coenzyme Q10-stabilizing effect of the fat and oil component and/or polyol so that reduced coenzyme Q10 can be stably maintained", is noted. However, combined teachings of Chopra in view of Motoyama et al clearly provide an understanding to an artisan of ordinary skill in the art at the time this invention was made for the suitability of polyglycerol fatty acid esters with compositions comprising drugs that are very slightly soluble in water (such as Co-Q1O, and vitamin E containing drugs and/or nutrients, etc.) in order to improve their dispersibility and thus bioavailability in living body owing to the surface active properties of said polyglycerol fatty acid esters (see Motoyama et al, column 4, lines 38- 42, in particular), and would have expected the same when combined with the reduced Q10 composition as currently claimed.
The argument that "...Since the composition of Chopra contains a large quantity of Vitamin E or Tween/Span, the composition cannot stably maintain reduced coenzyme Q10 without a reducing agent. Thus, the composition of Chopra stably maintains reduced coenzyme Q10 by using a reducing agent. On the other hand, by including the fat and/or oil component and/or the polyol, the composition of the present invention can stably maintain reduced coenzyme Q10 whether or not the composition contains a reducing agent. Thus, Chopra neither discloses nor suggests that the composition of the present invention can stably maintain reduced coenzyme Q10 by using the fat and/or oil component and/or the polyol", is noted and fully considered. However, it is noted that the invention as claimed (see claim 29, in particular) does not require a polyol, vitamin E or surfactants Tween or Span (i.e. these components, as well as fat or oil components, are currently optional as currently recited in the amended claims). The composition as claimed requires reduced Q10, a polyglycerol fatty acid ester and either a fat component, an oil component, or a polyol. The cited prior art of record fully disclose reduced Q10 containing composition, and suggest the combination and use of polyglycerol fatty acid esters for stabilizing very slightly soluble drugs such as Q10, and therefore the arguments presented by applicants are not found to be persuasive.
The arguments (see remarks, page 10, last paragraph, in particular) that "in Motoyama, the dispersibility of drug formulations is stabilized by use of polyglycerol fatty acid ester, thus Motoyama neither discloses nor suggests the effects of the present invention…and/or polyol", is not found to be persuasive because effects on bioavailability and its compatability with claimed composition has been fully suggested by Motoyama et al (see title and columns 2 and 4-5, in particular), and therefore, would have been fully contemplated by an artisan of ordinary skill in the art at the time this invention was made.
Arguments (see remarks, page 11, 2nd paragraph) regarding the declaration (132 declaration submitted by one of the inventors, Takahiro Ueda; see page 2, Table 1, in particular) showing "high stability of reduced coenzyme Q10" that is achieved by addition of MCT/Tween80/diglycerol monooleate in the presence of ascorbyl palmitate, is duly noted and fully considered. However, it is reiterated that the claims as currently recited (see instant claim 29, as currently amended) do not require the same components and particular ratios of said components that provide such beneficial results in terms of Q10 stability, as currently argued by applicants. The scope of the claimed invention is not commensurate with the showing presented by applicants. Thus, the 103a rejection of record is properly made & maintained.

Regarding the ODP rejection of record (see remarks, page 11, last paragraph), it is noted that the composition in the co-pending application 11/586511 recites "A stable composition comprising reduced coenzyme Q10 which comprises ascorbic acid or a related compound thereof together with the reduced coenzyme Q10, an oil and fat, a polyglycerol fatty acid ester with a polymerization degree of glycerol being not lower than 3 and/or a condensed ricinoleic acid polyglyceride" (see claim 16 of 11/586511), which is deemed co-extensive in scope (in view of the 103a rejection of record over Chopra and Motoyama et al), and is therefore deemed proper. Since, applicants have deferred the response to this rejection, the provisional ODP rejection of record is maintained.

Appropriate amendments to claims (claim 29, in particular) in order to distinguish the claimed composition from the cited art of record will help the future prosecution of this case.

/Satyendra K. Singh/
Examiner, AU 1657